Effect of a New Bleaching Gel on Tooth Whitening

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ABSTRACT

The purpose of this study was to test the efficacy of a novel bleaching agent containing a unique tri-barrel hydremide peroxide gel (KöR). Bovine incisors were mounted into a custom resin arch-shaped-mounting device. Four groups of 10 teeth were created using mounting devices containing 5 teeth each (n=10). Teeth were immersed in a solution of black tea for six days and allowed to stabilize for seven days. Baseline color readings of L*, a* and b* were obtained using a spectrophotometer. Groups 1 (KöR 13% hydremide peroxide, KöR 16% carbamide peroxide, KöR 34% hydremide peroxide) and 2 (Opalescence Boost 40% hydrogen peroxide (HP) and Opalescence Potassium Fluoride (PF) 15% carbamide peroxide (CP), Ultradent) had bleaching gel applied to the teeth alone and in trays to simulate a combination of in-office and home bleaching (Combined). Groups 3 (KöR 16% CP) and 4 (Opalescence PF 15% CP, Ultradent) had bleaching gel applied in trays to simulate home bleaching only (Home). Spectrophotometer readings of L* a* b* were performed again at the end of active bleaching (immediate) and at 3 and 6 months post-bleaching. The mounted teeth specimens were stored in artificial saliva at 37ºC between active bleaching treatments. Immediately post-bleaching, the use of Opalescence gel resulted in greater change in delta E* and delta b* (less yellow) for Combined and Home bleaching techniques compared to KöR. After six months, Opalescence had significantly greater delta E* and delta b* compared to KöR for Home bleaching only. There was no significant difference in delta L* between Opalescence and KöR at any time period with either technique. The use of the novel tri-barrel hydremide peroxide bleaching system (KöR) did not offer any advantages in the lightening of bovine teeth compared to a traditional bleaching system (Opalescence) of hydrogen or carbamide peroxide.

INTRODUCTION

Much emphasis is placed on outward appearance and often, a person's smile is what meets the eye first. Many people are enamored by whiter enamel creating a high demand for esthetic bleaching. As such, at-home and in-office whitening products have infiltrated the U.S. marketplace since the late 1980's[1] and the bleaching empire has exploded ever since. Whitening products include toothpastes, gels, and films, as well as in-office based systems.[1] In 2005 alone, the in-office and home bleaching market generated two billion dollars in sales.[2] With such high demand and potential for profitability, there is a constant race for companies to create the latest and greatest whitening agents while adhering to the ADA safety and efficacy guidelines.[3]

Vital bleaching is a relatively conservative way to achieve whiter teeth versus therapy like microabrasion, veneers, or crowns. Generally there are two vital bleaching modalities: "power bleaching" (in-office) with a 25-35% hydrogen peroxide (HP) and "home bleaching" with 10-20% carbamide peroxide (CP) or 2-10% HP in a custom-made mouth guard over 2-6 weeks.[4,5] The advantages of home whitening include ease of application, reduced chair time and cost, high success rate, and safety of materials.[6]

Furthermore, bleaching teeth with 10% carbamide peroxide (the only ADA-approved bleaching agent) in a custom-fitted tray has proven to be the safest, most cost-efficient whitening option for a large variety of tooth discoloration conditions.[7] The degree of whitening may be the similar for home bleaching and in-office bleaching, but in-office bleaching has more rapid regression.[5,8] Home bleaching may be very successful for a compliant patient as it offers the safest, least expensive way to get whiter teeth with slower regression. While the outcomes seem revolutionary, the bleaching process and materials are not new. HP has been a dental workhorse for over 70 years.[4] HP's bleaching success is attributed to its ability to penetrate tooth structure and produce free radicals that oxidize organic stains within the tooth.[9] During the bleaching process, CP breaks down into hydrogen peroxide and urea with the HP concentration being approximately one-third of the original CP concentration[6]. Therefore, a 15% CP product is ~5% HP. The first home bleaching with 10% CP was first reported by Haywood and Heymann in 1989.[10] And while there are many different concentrations of bleaching agents, 10% CP seems to be the gold standard. In fact, 10% CP (specifically, 10% CP Opalescence, Ultradent Products, South Jordan, UT) is presently the only bleaching product that has earned the ADA seal of approval. If a patient has the time, bleaching with 10% CP can be just as effective, if not more effective, than in-office bleaching with 35% HP. Bernardon et al. (2010) illustrated such results with a clinical study involving 90 patients that found that home bleaching with 10% CP in a tray was comparable to in-office bleaching with 35% HP.[8] Both home and in-office bleaching have been extremely successful. As such, several manufacturers have attempted to combine the two techniques to develop a more efficacious procedure.[11] Combination bleaching can be described as vital bleaching with 10-20% CP or 2-10% HP in a custom tray over 2-6 weeks with supplemental use of in-office vital bleaching with 25-35% HP before or after home whitening.

Due to the prevalence of HP and CP in many bleaching products, the dental literature is saturated with research on their respective safety and efficacy. Just recently, a literature review concluded that when manufacturer's instructions are followed, HP- or CP-based tooth whitening is safe and effective.[1] But now there is a new player. KöR Whitening (Evolve Dental Technology), a novel hydremide peroxide in-office bleaching gel that claims "wow" results and permanent whiteness unaffected by consumption of coffee, tea, or red wine with low to no sensitivity. KöR has also received praise with Dentistry Today, making Dentistry Today's Top 100 Products List for 2014 and 2015,[12] as well as making the cut for the Top 25 Aesthetic/Restorative Products for 2015.[13] The KöR in-office bleaching gel is a unique dual-activated, tri-barrel system. Three separate syringes are mixed together immediately before application. While it is not possible to elucidate the exact components of the proprietary formulation, the peroxide gel base is dispensed in a tri-barrel (3-chamber) system that allows the use of two distinctly different chemical accelerators. Refrigeration is provided throughout all phases of storage and shipping to reduce peroxide degradation. The KöR system also requires a proprietary tray (KöR-Seal trays) that reportedly provides a unique seal of the cervical 1-1.25mm portion of teeth that functions to seal out both saliva and sulcular fluid. The KöR-Seal trays in combination with continuous refrigeration reportedly provide 6 to 10 hours of whitening activity compared to the typical 25-35 minutes.[14] Other than company articles provided by the

inventor, Rod Kurthy, there is no independent research published on the KöR Whitening system (Kurthy, 2014).[15,16]

The purpose of this *in vitro* study was to compare the tooth whitening capability of KöR bleaching gels to popular comparable Ultradent Products on bovine incisor crowns. Changes in color of the bovine teeth from the bleaching process were determined using the CIE (Commission Internationale de l'Eclairage) L* a* b* color space. L* indicates lightness (L+ = lightness and L- = darkness), the a* coordinate represents the red/green range (a*+ = redness and a*- = greenness) and the b* coordinate represents for the yellow/blue range (b* + = yellowness and b*- = blueness).[17] The L* a* b* system allows the numeric definition of a color as well as the overall difference between two colors (delta E). The null hypothesis was that there would be no difference in the change in L* (delta L), a*, (delta a), b* (delta b) and E* (delta E*) based on type of bleaching gel per technique over time.

MATERIALS AND METHODS

A total of four groups were created in this study to evaluate the whitening of crowns of bovine incisors using either a combined bleaching technique of in-office and home bleaching (Combined) or home bleaching alone (Home) using KöR and Opalescence bleaching gels.

For the Combined bleaching, two groups were compared using the KöR Max Ultra Kit and Opalescence Boost 40% HP / Opalescence PF 15% CP bleaching gel (Ultradent Products). KöR bleaching kits are sold in three varieties: KöR Standard, KöR Max, and KöR Max Ultra. See Table 1 below. The KöR Max Ultra Kit was chosen for this study for combined bleaching because it is marketed for use with difficult cases.

KöR Standard Kit	KöR Max Kit	KöR Max Ultra Kit
13% hydremide peroxide for three 20-min chairside sessions	34% hydremide peroxide for three 20-min chairside sessions	13% hydremide peroxide for three 20-min chairside sessions
16% CP home bleaching for 21 nights	16% CP home bleaching for 21 nights	16% CP home bleaching for 28 nights
N/A	N/A	34% hydremide peroxide for three 20-min chairside sessions

Table 1: KöR bleaching kit combinations

Opalescence Boost 40% HP was included in this study because it is a popular in-office bleaching system as featured in Dentistry Today's Top 100 Products List for 2010 and 2013.[12] The Opalescence Boost 40% HP was used with Opalescence PF 15% CP home bleaching gel to create a combined bleaching technique. The Opalescence Boost 40% HP in-office bleaching gel is a dual-barrel system. Two separate

syringes are mixed together immediately before application. Two additional groups were created to evaluate the home bleaching technique only. KöR 16% CP was compared to Opalescence PF 15% CP - two home bleaching gels with similar concentration of carbamide peroxide. See Figure 1 below. The four groups are outlined below:

Group 1 (Combined): KöR 13% hydremide peroxide and 34% hydremide peroxide (KöR Max Ultra Kit) were used to simulate in-office bleaching while KöR 16% CP was used as in custom tray as a home bleaching agent.

Group 2 (Combined): Opalescence Boost 40% HP was used as an in-office bleaching agent and Opalescence PF 15% CP was used in a custom tray to simulate home bleaching.

Group 3 (Home): KöR 16% CP was used in custom bleaching trays to simulate home bleaching.

Group 4: (Home): Opalescence PF 15% CP was used in custom bleaching trays to simulate home bleaching.

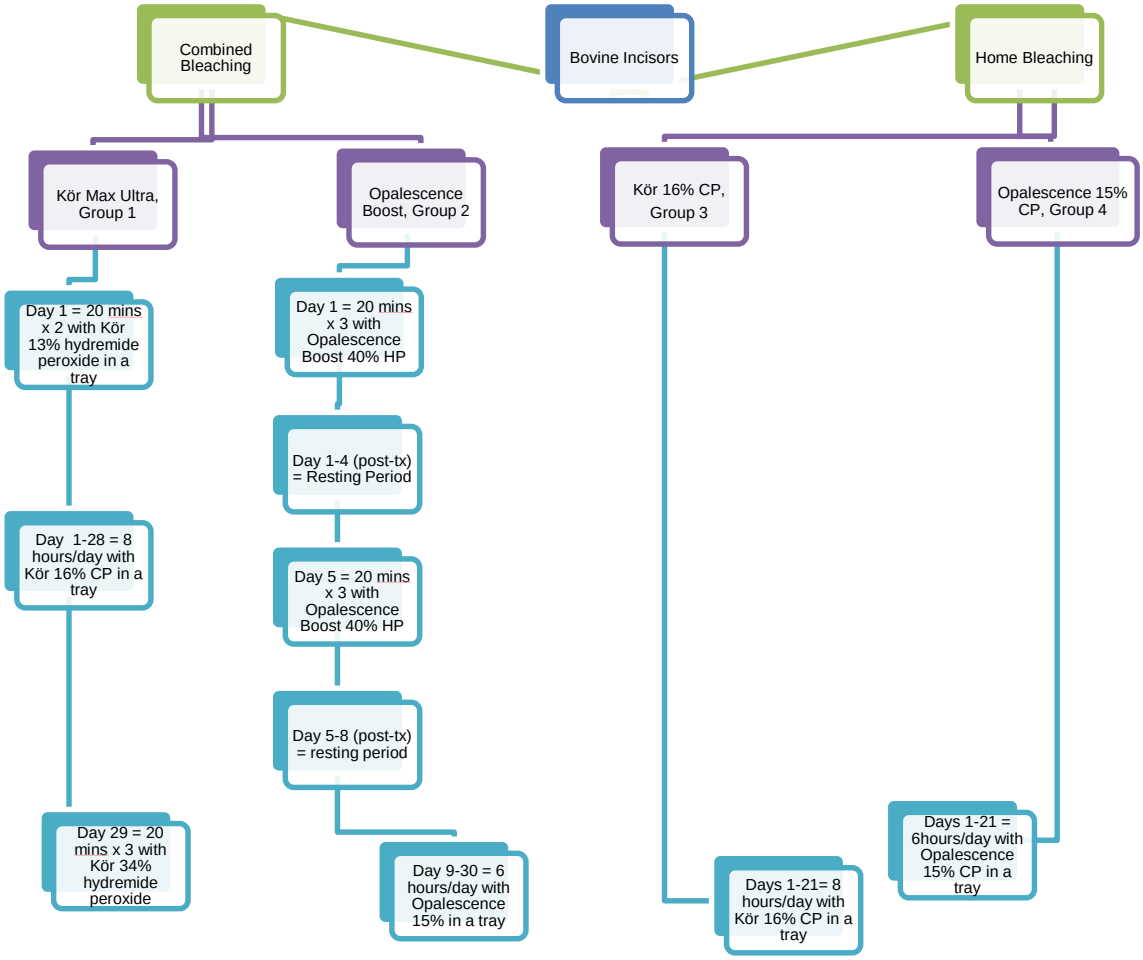

Figure 1: Flowchart of the four bleaching gel combinations over time following the manufacturer's instructions.

Forty bovine incisors (Animal Technologies, Tyler, TX) were stored and disinfected in a 0.5% chloramine-T (Alfa Chemistry, Stony Brook, NY). The teeth were then examined under a light microscope at 10x magnification (Nikon SMZ-1B, Melville, NY) and discarded if any gaps, cracks or pigmentation were found that would interfere with the bleaching evaluation. Custom arch-shaped mounting devices were created to provide a mechanism for bleaching tray fabrication and insertion. See Figure 2. The custom resin arch-shaped-mounting devices were created using a stereolithography printer (Viper si2 SLA System, 3D Systems Inc., Darmstadt, Germany) with a clear resin material (Somos WaterShed XC 11122, DMS Functional Materials, Elgin, IL). Each device contained five mounting wells for the bovine teeth. Two mounting devices were printed per group for a total of 10 teeth per group (n=10). Each tooth was mounted in the wells with vinyl polysiloxane (Regisil PB, Dentsply, York, PA). After all the bovine teeth were mounted in the devices, custom trays were created per the manufacturer's guidelines using each company's proprietary block out and tray materials. See Figure 3.

Figure 2. Teeth mounted in custom resin device

Figure 3: Custom tray fabrication

KöR-Seal whitening trays were fabricated for use with KöR bleaching products. KöR-Seal trays require several steps and can be accomplished in-office or by mailing impressions to the KöR-Lab. All KöR-Seal trays for this study were fabricated by the research investigators following the manufacturer's instructions. Impressions of the mounted bovine teeth were made using KöR polycarbonate impression trays. After painting the impression trays with KöR Impression Tray Adhesive, the base impression was made with KöR-Seal VPS Putty. Evolve BLUgrinder Burs were used to grind out the base impression. The wash impression was made with KöR Light Body Wash VPS. Impressions were allowed to de-gas 30-60 minutes, then were sprayed with debubblizer (Smoothex, Whipmix Corporation, Louisville, KY), and poured in dental stone (Denstone, Heraeus Kulzer, South Bend, IN). The model bases were trimmed and blocked out with the same dental stone (0.5-1mm thick, 1-1.25mm from gingival line) per the manufacturer's recommendations. The KöR-Seal trays were made with a soft 0.40'' ethylene vinyl acetate (EVA) sheet via a positive-pressure thermal-forming machine (Biostar, Great Lakes Orthodontics, Tonawanda, NY). To create bleaching trays for home bleaching with Opalescence PF 15% CP, an alginate impression was made of the mounted bovine teeth and poured in dental stone (Die Keen, Heraeus Kulzer). Model bases were trimmed and Ultradent LC Block-Out Resin was applied per manufacturer recommendations (0.5mm thick,

1.5mm from gingival line). Custom trays were made with 0.035''Sof-Tray with the positive-pressure thermal-forming machine as before.

The superficial enamel of the bovine teeth was cleaned with prophy paste (Nupro, Dentsply, York, PA) using a disposable prophy angle (Nupro Revolv, Dentsply) to remove extrinsic stains. Due to the inherent high value of bovine teeth, a tea-staining protocol was utilized after mounting the teeth and prior to Home or Combined bleaching.[18] The mounting devices with the bovine teeth were immersed in a solution of black tea for six consecutive days at room temperature in order to create a standardized, stained surface of the enamel.[19] The tea solution was created by soaking 1 filter bag (Starbucks Awake English Breakfast Tea, Starbucks, Seattle, WA) in 8oz of boiling water for five minutes. The tea solution was changed every 24 hours. Then, the teeth were stored in synthetic saliva at oral temperature at 37°C for seven days in a laboratory incubator (Model 20GC, Quincy Lab, Chicago, IL) to stabilize the stained surfaces. The synthetic saliva was prepared as described by Lata[20] (2010): Na_3PO_4 - 3.90 mM $NaCl_2$ - 4.29 mM KCl - 17.98 mM $CaCl_2$ - 1.10 mM $MgCl_2$ - 0.08 mM H_2SO_4 - 0.50 mM $NaHCO_3$ - 3.27 mM, distilled water, with a pH set to a level of 7. 2. A pH meter (Accumet XL50, Fisher Scientific, Waltham, MA) was be used to measure pH.

A customized, resin insert was printed using stereolithography and sprayed with white paint. The insert was placed in the mounting device during spectrophotometer readings (Easyshade Compact, VITA, Yorba Linda, CA). Teeth were positioned so that the lingual surfaces were parallel to the white insert. A baseline reading was performed using the spectrophotometer. The tip of the spectrophotometer was placed into a customized clear vinyl polysiloxane stent that rested on the teeth to create a standardized position for recording. See Figure 4.

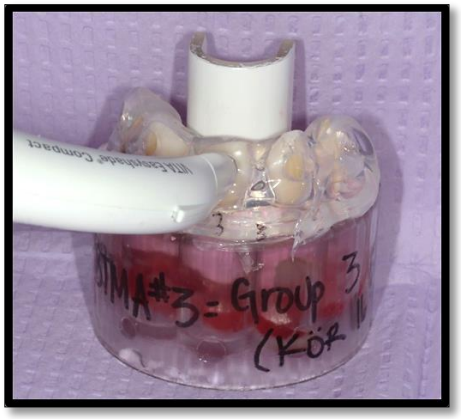

Figure 4. Clear custom stent to standardize placement of spectrophotometer tip

After the baseline reading, the bleaching procedures were performed according to the following four protocols. All bleaching agents were stored in a refrigerator when not in use. KöR bleaching gels arrived from the manufacturer in a refrigerated container.

Group 1 (KöR, Combined)

- Day 1: To simulate in-office bleaching, a 1-mm layer of KöR 13% hydremide peroxide gel was applied to the teeth using a custom tray for 20 minutes. Bleaching gel was suctioned off the teeth and a new mix of KöR 13% hydremide peroxide gel was again applied to the teeth using a custom tray for another 20 minute session. The bleaching gel was suctioned off once again and the teeth were thoroughly rinsed, dried and stored in synthetic saliva at 37°C.
- Days 1-28: To simulate home bleaching, KöR 16% CP was applied to the teeth for 8 hours using a custom tray. The first 8-hour session of home bleaching was the same day as the in-office bleaching. After each daily 8-hour tray bleaching session, the teeth were thoroughly rinsed and dried and stored in synthetic saliva at oral temperature at 37°C. The home bleaching process was repeated every day for 28 days.
- Day 29: To simulate in-office bleaching once again, 1mm of KöR 34% hydremide peroxide gel (instead of KöR 13% hydremide peroxide gel) was applied to the enamel surfaces. The teeth were bleached for three 20-minute sessions instead of two, as recommended by the manufacturer.

Group 2 (Opalescence, Combined)

- Day 1: To simulate in-office bleaching, 1 mm of Opalescence Boost 40% HP gel was applied to the teeth for 20 minutes. The bleaching gel was suctioned off the teeth and a second 1-mm layer of Opalescence Boost 40% HP gel was applied to the teeth for another 20 minute session. The bleaching gel was suctioned off teeth once again and a third and final 1-mm layer of Opalescence Boost 40%HP gel was applied to the teeth for the last 20-minute session. At the end of the third bleaching session, bleaching gel was suctioned off and the teeth thoroughly rinsed, dried and stored in synthetic saliva at 37°C.
- Days 1-4: A four day resting period was allowed between in-office treatments per manufacturer recommendations.
- Day 5: To simulate in-office bleaching, the Opalescence Boost 40% HP gel was applied to the teeth in the same manner as on Day 1.
- Days 5-8: Resting period. A second four-day resting period was allowed as after the first in-office treatment. No in-office bleaching gel was applied again until day 9.
- Days 9-30: To simulate home bleaching, 1 mm of Opalescence PF 15% CP was applied to the teeth for 6 hours using a custom tray following the manufacturer's instructions. After each daily 6-hour tray bleaching session, the teeth were thoroughly rinsed, dried and stored in synthetic saliva at oral temperature at 37°C. The bleaching process was repeated every day for 21 days.

Group 3 (KöR, Home)

- Days 1-21: To simulate home bleaching, KöR 16% CP was applied to the teeth for 8 hours with a custom tray following the same technique as described previously with the KöR Combined group.

Group 4 (Opalescence, Home)

- Days 1-21: To simulate home bleaching, Opalescence PF 15% CP was applied to the teeth for 6 hours using a custom tray using the same technique as described previously with the Opalescence Combined group.

All teeth specimens were stored in artificial saliva at 37ºC between active bleaching. The bovine teeth were measured immediately after completion of bleaching, and at 3 and 6 months post-bleaching using a spectrophotometer. L* a* b* values were recorded for each tooth at each time interval. Delta L*, delta a*, and delta b* were calculated by subtracting each reading from baseline per time interval. Delta E* was determined using the following formula: delta E* = $[(\text{delta } L^*)^2 + (\text{delta } a^*)^2 + (\text{delta } b^*)^2]^{1/2}$. Data were analyzed with a Repeated Measures ANOVA examining the effects of type of bleaching (Home vs. Combined) or type of bleaching agent (KöR vs. Opalescence) on delta E* or delta b* over time (alpha = 0.05). However, significant interactions were found ($p<0.05$). The delta E* and delta b* data were evaluated with a one-way ANOVA per bleaching gel and treatment type and unpaired t-tests between bleaching gels and treatment type. A Bonferroni correction was applied because multiple comparison tests were completed (alpha=0.01). Due to the large variability of the data, delta L* was analyzed with Kruskal-Wallis and Mann-Whitney U tests with a Bonferroni correction (alpha=0.01).

RESULTS

Immediately post-bleaching, the use of Opalescence gel resulted in greater change in delta E* and delta b* for Combined and Home bleaching techniques compared to KöR ($p<0.01$). After six months, Opalescence had significantly greater delta E* and delta b* compared to KöR for Home bleaching only ($p<0.01$). There was no significant difference in delta L* between Opalescence and KöR at any time with either technique ($p>0.01$). Also, there was no significant difference in delta E*, b* or L* for either material or technique based on time ($p>0.01$). See table 2.

Delta E

	Combined Bleaching			Home Bleaching		
	Immediate	3 months	6 months	Immediate	3 months	6 months
Opalescence	14.5 (5.5) Aa	13.2 (5.2) Aa	13.8 (4.6) Aa	20.4 (7.9) Aa	19.9 (5.5) Aa	20.7 (6.6) Aa
KöR	8.5 (4.0) Ab	11.3 (3.2) Aa	10.4 (3.3) Aa	10.9 (3.2) Ab	14.5 (3.2) Aa	14.0 (3.5) Ab

Delta b

	Combined Bleaching			Home Bleaching		
	Immediate	3 months	6 months	Immediate	3 months	6 months
Opalescence	-11.4 (3.9) Aa	-7.1 (3.1) Aa	-9.5 (3.3) Aa	-17.8 (5.0) Aa	-17.4 (3.0) Aa	-18.7 (4.9) Aa
KöR	-4.7 (3.9) Ab	-6.0 (2.8) Aa	-6.5 (2.1) Aa	-9.6 (3.0) Ab	-12.9 (3.0) Ab	-13.2 (3.2) Ab

Delta L

	Combined Bleaching			Home Bleaching		
	Immediate	3 months	6 months	Immediate	3 months	6 months
Opalescence	7.9 (4.1) Aa	10.8 (4.0) Aa	9.4 (3.4) Aa	6.9 (8.8) Aa	8.1 (6.3) Aa	6.3 (7.1) Aa
KöR	6.3 (2.9) Aa	9.5 (2.2) Aa	7.9 (2.4) Aa	4.6 (2.6) Aa	5.3 (3.5) Aa	3.5 (3.3) Aa

Table 2: Delta E*, b* and L* values for Combined and Home bleaching techniques for both Opalescence and KöR bleaching gels

DISCUSSION

The purpose of this *in vitro* study was to evaluate the tooth whitening capability of a new bleaching gel system (KöR) containing a unique hydremide-peroxide formulation. KöR bleaching gels were compared to popular bleaching gels from Ultradent Products on bovine incisor crowns using the CIE L* a* b* color space system.

The null hypothesis was rejected. There was a difference in delta b* and delta E* based on type of bleaching gel per technique. However, the differences varied over time. For both Combined and Home bleaching, the use of Opalescence gel resulted in a greater change in delta E* compared to KöR immediately after bleaching. A greater change in delta E* is associated with an overall greater change in color. However, delta E* does not provide specific information as to the direction of the color change. Previous literature has shown that whitening from bleaching agents is manifested mainly by a reduction in yellowness (lower b*) and an increase in lightness (higher L*) and to a minor extent, a reduction in redness (lower a*).[21-26] While all values (L* a* b*) were obtained at all intervals of this study, ultimately only delta E*, delta b*, and delta L* were reported. Due to the variability and fluctuation of a*, the delta a* values were not analyzed and deemed singularly non-contributory.[22] These findings are consistent with a study by Lenhard (1996)[27] that found that the variance in a* values had only a minor influence on color change.

The use of Opalescence gel resulted in a greater change in delta b* (i.e., less yellow) compared to KöR immediately after bleaching for both Combined and Home bleaching. However, after six months post-bleaching, Opalescence had significantly greater delta b* compared to KöR for Home bleaching only. Home bleaching was associated with a greater reduction in yellowness (delta b*) than Combined bleaching, however, there was a tendency for Combined bleaching to result in greater lightness (delta L*) than Home bleaching, suggesting no overall benefit from either technique. Two recent clinical studies found no statistically significant difference between combined and home bleaching.[11,28] However, more sensitivity was reported with combined bleaching compared to home bleaching.[28] In this study, there was no statistically significant difference in delta L* between Opalescence and KöR at any time with either technique. Although the use of Opalescence gel may have initially resulted in a greater reduction in yellowness compared to KöR with either Combined or Home bleaching, the difference became less significant over time with Combined bleaching. Although not statistically significant, delta E* and b* values had a tendency to improve with KöR over the first three months after bleaching and remain more stable with Opalescence. In all groups, bleaching treatment resulted in a significant overall color change (delta E*) above the limit of visible detectability, which has been reported to be greater than 3.3 units.[29,30] Wiegand et al.,[22] (2008) evaluated the effects of bleaching agents using enamel and dentin bovine segments using similar methods to this study. After 12 months of storage in artificial saliva, the researchers found no difference in color retention between the different bleaching techniques (home, in-office and walking) using the CIE L* a* b* color system. However, the color change was not stable, with the greatest regression with delta L*.[22] These results differ from this study, however, when after six months of storage in artificial saliva, there was no significant change in delta E*, b* or L* for either material or technique based on time. Longer

storage time may be necessary to demonstrate regression of the whitening effect.

Bovine teeth have been used in multiple *in vitro* studies to evaluate bleaching and are much more readily available than human anterior teeth.[31-33,18] Also, bovine teeth have similar physical chemistry to human teeth and provide similar results when staining or whitening procedures are evaluated in the laboratory.[34] To the authors' knowledge, no other published laboratory studies have utilized the novel method of mounting bovine teeth in an arch-like form for the fabrication of custom trays as done in this study.

CONCLUSIONS

Within the limitations of this study, the following statements can be made. Immediately after bleaching, the use of Opalescence gel resulted in greater change in delta E* and delta b* (less yellow) compared to KöR for both bleaching techniques. After six months, Opalescence had significantly greater delta E* and delta b* for Home bleaching only. The use of the novel tri-barrel hydremide peroxide bleaching system (KöR) did not offer any advantages in the lightening of bovine teeth compared to a traditional bleaching system (Opalescence) of hydrogen or carbamide peroxide.

Disclaimer

The opinions or assertions contained herein are the private ones of the authors and are not to be construed as official or reflecting the view of the DoD or the USUHS. The authors do not have any financial interest in the companies whose materials are discussed in this article.

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